

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte HANS BERG

Appeal No. 2002-0456
Application No. 09/155,995

HEARD October 24, 2002

Before SCHEINER, ADAMS and GREEN, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 1-20, all the claims remaining in the application. Claims 1 and 11 are representative of the subject matter on appeal and read as follows:

1. A process for the production of a porous cross-linked polysaccharide gel, comprising the following steps:
 - a) preparing a solution or dispersion of the polysaccharide,
 - b) adding a bifunctional cross-linking agent having one active site and one inactive site to the solution or dispersion from step a),
 - c) reacting hydroxylgroups of the polysaccharide with the active site of the cross-linking agent,
 - d) forming a polysaccharide gel,
 - e) activating the inactive site of the cross-linking agent,
 - f) reacting the activated site from step e) with hydroxylgroups of the polysaccharide gel, whereby cross-linking of the gel takes place.

11. A porous, cross-linked polysaccharide gel obtainable by the following steps:
- a) preparing a solution or dispersion of the polysaccharide,
 - b) adding a bifunctional cross-linking agent having one active site and one inactive site to the solution or dispersion from step a),
 - c) reacting hydroxylgroups of the polysaccharide with the active site of the cross-linking agent,
 - d) forming a polysaccharide gel,
 - e) activating the inactive site of the cross-linking agent,
 - f) reacting the activated site from step e) with hydroxylgroups of the polysaccharide gel, whereby cross-linking of the gel takes place.

Claims 1-20 stand rejected under 35 U.S.C. § 103 as unpatentable over Lindgren¹ alone, and over Lindgren “in view of appellant’s own admissions.” Examiner’s answer, pages 3-6.

We reverse both of these rejections.

BACKGROUND

“Gel matrices of polysaccharides have long been used as separation media . . . [in] chromatographic separation methods.” Specification, page 1. As further explained in the specification (pages 1-2):

Generally, chromatographic separations are carried out in columns packed with the separation matrix in [the] form of particulate beads. Separation media of a fast kinetics with rapid flow rates results in a high productivity and may be achieved by a reduction in the particle size. However, small beads result in a higher back pressure due to the narrowing of the convective flow channels between the particles in a packed bed. To be able to separate large molecules the particles should have large pores, but large pores may result in a weakened structure of the particles. As the polysaccharides are soft materials the particles may easily collapse, especially at high flow rates . . . It is well known to increase the stability of polysaccharide particles by cross-linking the polymer . . . [stabilizing] the polysaccharide gel matrices by chemically binding the polymer chains with each other at their respective free hydroxyl groups. The cross-linking takes place between the hydroxyl and the functional groups of the cross-linkers. This affects the particle rigidity, but to a lesser extent or not at all the size of the pores . . .

¹ U.S. Patent No. 4,973,683 to Lindgen, issued November 27, 1990.

[Additionally,] it was found that the rigidity of the polysaccharides was considerably improved when the cross-linking agent used was monofunctional but also contained an additional masked functional group that could be activated later. The cross-linking was made in two steps. First the polysaccharide was derivatized with the monofunctional group. Then, in the next step the masked group was activated and made to react with the hydroxyl groups of the polysaccharide.

According to appellant, “the state of the art [] is that the cross-linking is made on the polysaccharide polymer after the formation of the gel . . . [t]hus, the cross-linking is made on the ready made structure.” Specification, page 2. The present invention, on the other hand, is directed to cross-linked polysaccharide gels, and methods of making them, in which a bifunctional cross-linking agent “is introduced into the polysaccharide solution or dispersion before the gel formation . . . the active site of the [bifunctional cross-linking] agent is allowed to react with the hydroxyl groups of the polysaccharide” and “thereby . . . is chemically bound to the polymer chains before the gel formation process is started.” Id., page 4. “In this manner an internal cross-linking agent is introduced into the polysaccharide,” resulting in cross-linked polysaccharide gels “with improved capability to withstand high flow rates/back pressures, but with retained separation qualities.” Id., page 3.

DISCUSSION

According to the examiner, Lindgren “discloses the essential details of the instant process . . . [and] is directed to the same subject matter” except for “the use of an organic solvent in the gelling[] process step.” Answer, page 4. Based on his findings, the examiner concludes that “[t]he disclosure in [Lindgren] . . . is deemed to render the instant claimed compound produced and the instant claimed process lacking in patentable distinction in the absence of unexpected results.” Id.

Findings of fact underlying an obviousness rejection, as well as conclusions of law, must be made in accordance with the Administrative Procedure Act, 5 U.S.C. 706 (A),(E) (1994), see Zurko v. Dickinson, 527 U.S. 150, 158, 119 S.Ct. 1816, 1821, 50 USPQ2d 1930, 1934 (1999), and must be supported by substantial evidence within the record. See In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). In addition, in order for meaningful appellate review to occur, the examiner must present a full and reasoned explanation of the rejection. See, e.g., In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1432 (Fed. Cir. 2002). We would further emphasize what should be self-evident: the examiner must present a full and reasoned explanation of the rejection in the statement of the rejection, specifically identifying underlying facts and any supporting evidence, in order for appellants to have a meaningful opportunity to respond.

The claimed process requires the addition of a “bifunctional” cross-linking agent to a polysaccharide solution or suspension before the polysaccharides are allowed or induced to form a gel. The bifunctional cross-linking agent must have one active site which reacts with - and substitutes - the polysaccharides before gel formation, and another site, initially inactive, that is activated (and allowed to react with and cross-link the polysaccharides) after gel formation. Having failed to address this aspect of the invention in the first instance, the examiner belatedly argues that “inspection of Example 1 of [Lindgren] suggests that the process of the cited reference also does not produce a gel until after the [substitution] portion of the process has been completed.”

Nevertheless, Lindgren, at columns 3 and 4, describes a generic process whereby pre-formed polysaccharide gels are substituted and cross-linked with bifunctional cross-linking agents. Example 1, which immediately follows, describes the

results of cross-linking Sepharose ® with allylbromide. According to the examiner's argument, then, the Sepharose ® used in the example is not a gel. As this would be inconsistent with Lindgren's generic description of the prior art process (not to mention Examples 2 through 6), and as the examiner has provided no factual basis for his assertion, we are not persuaded by this argument. Similarly, the examiner has not established a factual basis for his assertion that "the product produced by the prior art method is . . . patentably indistinguishable from the instant claimed product" (Answer, page 4).

Finally, we are at a loss as to how the examiner can interpret "[a]ppellant's admission . . . that the contacting of agarose or other polysacharides with crosslinking agents is conventional in the art" as "an admission that . . . the appropriate conditions for their use are not a patentably distinguishing feature." Answer, page 6.

The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Thus, the examiner is charged with adequately addressing every limitation of the claimed invention. This the examiner has not done. In our judgment, Lindgren's disclosure, with or without "appellant's admission," is insufficient to support a conclusion of obviousness of claims containing the limitations discussed above and the examiner has failed to provide an adequate factual basis to establish a prima facie case of obviousness within the meaning of 35 U.S.C. § 103.

On this record, we reverse both of the examiner's rejections of the claims on appeal.

REVERSED

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Toni R. Scheiner)	
Administrative Patent Judge)	
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